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**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

**ATTORNEY DOCKET NO. 052209-0143**

Applicant: Marco FILICORI  
Title: UNITARY COMBINATIONS OF FSH AND hCG  
Appl. No.: 10/559,610  
Filing Date: 01/31/2007  
Examiner: Unassigned  
Art Unit: 1614  
Confirmation Number: 1532

**INFORMATION DISCLOSURE STATEMENT**  
**UNDER 37 CFR §1.56**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicant in order to comply with Applicant's duty of disclosure pursuant to 37 CFR §1.56.

A copy of each non-U.S. patent document and each non-patent document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicant does not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

**TIMING OF THE DISCLOSURE**

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

**RELEVANCE OF EACH DOCUMENT**

The submitted documents are cited in the specification.

An English translation of foreign-language document B28 is not readily available. However, the absence of such translation does not relieve the PTO from its duty to consider the submitted documents (37 CFR §1.98 and MPEP §609). Moreover, this document is cited only for teaching methods of purifying hCG. See, e.g., page 11 of the specification.

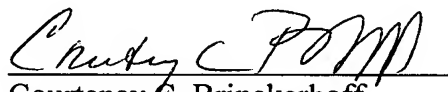
Applicant respectfully requests that each listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

Although Applicant believes that no fee is required for this Request, the Commissioner is hereby authorized to charge any additional fees which may be required for this Request to Deposit Account No. 19-0741.

Respectfully submitted,

May 31, 2007  
Date

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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b>	
				Application Number	10/559,610
				Filing Date	06/02/2004
				First Named Inventor	Marco FILICORI
				Art Unit	1614
				Examiner Name	Unassigned
Sheet <u>1</u> of <u>3</u>				Attorney Docket Number	052209-0143

O I P E  
 MAY 31 2007  
 U.S. PATENT & TRADEMARK OFFICE

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
	B1	5,656,597	08-12-1997	SKRABANJA et al.	
	B2	5,929,028	07-27-1999	SKRABANJA et al.	

**FOREIGN PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Documents	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> Number <sup>4</sup> Kind Code <sup>5</sup> (if known)				

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>
	B3	ASCOLI, "Characterization of Several Clonal Lines of Cultured Leydig Tumor Cells: Gonadotropin Receptors and Steroidogenic Responses," Endocrinology, 1981, pages 88-95, Vol. 108, No. 1, The Endocrine Society.	
	B4	CAMPBELL et al., "Examination of the Relative Role of FSH and LH in the Mechanism of Ovulatory Follicle Selection in Sheep," Journal of Reproductive and Fertility, 1999, pages 355-367, Vol. 117, Journals of Reproduction and Fertility Ltd.	
	B5	CHANG et al., "Recombinant Human Chorionic Gonadotropin (rhCG) in Assisted Reproductive Technology: Results of a Clinical Trial Comparing Two Doses of rhCG (Ovidrel <sup>R</sup> ) to Urinary hCG (Profasi <sup>R</sup> ) for Induction of Final Follicular Maturation in <i>in vitro</i> Fertilization-Embryo Transfer," Fertility and Sterility, July 2001, pages 67-74, Vol. 76, No. 1, American Society for Reproductive Medicine.	
	B6	CHAPPEL et al., "Biosynthesis and Secretion of Follicle-Stimulating Hormone," Endocrine Reviews, 1983, pages 179-211, Vol. 4, No. 2, The Endocrine Society.	
	B7	CLASESSON L., et al., "Crystalline Human Chorionic Gonadotrophin and its Biological Action," ACTA Endocrinologica, 1948, Vol. I, pages. 1-18.	
	B8	DIGHE et al., "Use of $\alpha$ - and $\beta$ -Subunit Specific Antibodies in Studying Interaction of hCG with Leydig Cell Receptors", Archives of Biochemistry and Biophysics, September 1983, pages 490-499, Vol. 225, No. 2, Academic Press, Inc.	

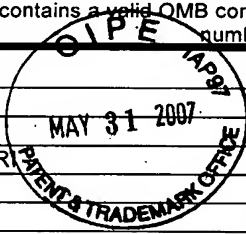
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Substitute for form 1449/PTO <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  (use as many sheets as necessary)				<b>Complete if Known</b> Application Number 10/559,610 Filing Date 06/02/2004 First Named Inventor Marco FILICORI Art Unit 1614 Examiner Name Unassigned Attorney Docket Number 052209-0143	
Sheet	2	of	3		




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Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>6</sup>	
	B9	FEVOLD, H. L. et al., "Studies in the Physical Chemistry of the Anterior Pituitary Hormones," Endocrinology, May 1940, Vol. 26, pages 999-1004.		
	B10	FILICORI et al., "Modulation of Folliculogenesis and Steroidogenesis in Women by Graded Menotrophin Administration," Human Reproduction, 2002, pages 2009-15, Vol. 17, No. 8, European Society of Human J Reproduction and Embryology.		
	B11	FILICORI et al., "The Use of LH Activity to Drive Folliculogenesis: Exploring Uncharted Territories In Ovulation Induction," Human Reproduction Update, 2002, pages 543-557, Vol. 8, No. 6, European Society of Human Reproduction and Embryology.		
	B12	FILICORI, "Use of Luteinizing Hormone In the Treatment of Infertility: Time for Reassessment?," Fertility and Sterility, February 2003, pages 253-255, Vol. 79, No. 2, American Society for Reproductive Medicine.		
	B13	FRAENKEL-CONRAT et al., "Purification of Follicle-Stimulating Hormone (FSH) of the Anterior Pituitary," Proc. Soc. Exp. Biol. Med., 1940, Vol. 45, pages 627-630.		
	B14	GORDON et al., Abstracts of the 13 <sup>th</sup> Annual Meeting of the ESHRE, 1997, pages 52-54, Edinburgh.		
	B15	GREEP, B. F., et al., "Separation in Nearly Pure Form of Luteinizing (interstitial Cell-Stimulating) and Follicle-Stimulating (Gametogenic) Hormones of the Pituitary Gland," J. Biol. Chem., 1940, Vol. 133, pages. 289-291.		
	B16	GUPTA et al., "Hyperexpression of Biologically Active Human Chorionic Gonadotropin Using The Methylootropic Yeast," Pichia Pinions, Journal of Molecular Endocrinology, 1999, pages 273-283, Vol. 22, Society of Endocrinology.		
	B17	HILLIER et al., 'Follicular Oestrogen Synthesis: The Two-Cell, Two-Gonadotrophin' Model Revisited,' Molecular and Cellular Endocrinology, 1994, pages 51-54, Vol. 100, Elsevier Science Ireland Ltd.		
	B18	KATZMAN, P.A., et al., "The Preparation of Chorionic Gonadotropin by Chromatographic Adsorption," J. Biol. Chem., 1943, Vol. 148, pages 501-507.		

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	B19	KEENE et al., "Expression of Biologically Active Human Follitropin in Chinese Hamster Ovary Cells," The Journal of Biological Chemistry, March 25, 1989, pages 4769-4775, Vol. 264, No. 9, The American Society for Biochemistry and Molecular Biology, Inc.		
	B20	LI, et al., "Isolation of Pituitary Follicle Stimulating Hormone (FSH)," Science, 1949, Vol. 109, pp. 445-446.		
	B21	MARTIN et al., "ART: Ovarian Stimulation," Fertility & Sterility, October 14, 2002, page S19.		
	B22	MCSHAN, W.H., et al., "The Preparation and Properties of Pituitary Follicle-Stimulating Fractions Made By Trypsin Disgestion," J. Biol. Chem., 1940, Vol. 135, pages 473-482.		
	B23	REMINGTON'S PHARMACEUTICAL SCIENCES, 15 <sup>th</sup> Ed. (Mark Publishing Co. 1975), pages 1405-1412 and 1461-1487.		
	B24	SHOHAM, "The Clinical Therapeutic Window For Luteinizing Hormone in Controlled Ovarian Stimulation," Fertility and Sterility, June 2002, pages 1170-1177, Vol. 77, No. 6, American Society for Reproductive Medicine.		
	B25	SNYDER et al., "Characterization of Human LH Isohormones From Fresh Pituitary Tissue," Molecular and Cellular Endocrinology, 1987, pages 115-121, Vol. 54, Elsevier Scientific Publishers Ireland Ltd.		
	B26	VAN HELL, H., et al., "Effects of Human Menopausal Gonadotrophin Preparations in Different Bioassay Methods," ACTA Endocrinologica, 1964, Vol. 47, No. 3, pages 407-418.		
	B27	WARNE et al., "Induction of Ovulation in World Health Organization Group II Anovulatory Women Undergoing Follicular Stimulation with Recombinant Human Follicle-Stimulating Hormone: A Comparison of Recombinant Human Chorionic Gonadotropin (rhCG) and Urinary hCG," Fertility and Sterility, June 2001, pages 1111-1118, Vol. 75, No. 6, American Society for Reproductive Medicine.		
	B28	Zondek and Aschheim, Klin, Wochenschr, 1928, Vol. 7, pages 931-932.		

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